GPhA
Making American Healthcare More Affordable

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Comment of the Generic Pharmaceutical Association in Support of Citizen Petition Docket No. 2004P-0075/CP1

The Generic Pharmaceutical Association ("GPhA") hereby submits these comments in support of the February 17, 2004 citizen petition filed by Mylan Pharmaceuticals, Inc. ("Mylan"). In that petition, Mylan urges FDA to end brand-name companies' practice of using so-called "authorized generics" to undercut the 180-day generic exclusivity that Congress created as part of the Hatch-Waxman Amendments to the Federal Food Drug and Cosmetic Act. 21 U.S.C. § 355(j)(5)(B)(iv). Apotex Corp. filed an additional comment in support of the Mylan petition on March 24, 2004, and GPhA supports the position taken in that comment as well.

The term "authorized generic" refers to a product that, while called a generic, is in fact marketed under color of an approved new drug application ("NDA"). The term does not refer to a true generic drug marketed under an approved abbreviated new drug application ("ANDA"), nor does it include an NDA product sold by a company with the right to generic exclusivity. Significantly, because an "authorized generic" is not marketed under an ANDA, brand companies have sold such products during the 180-day generic exclusivity awarded the first ANDA filer pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).

Congress provided for a 180-day generic exclusivity period for the first ANDA applicants to challenge, or design or invent around, brand company patents. Knowing that the 180-day exclusivity period is the only incentive that Congress created to encourage prompt patent challenges, and thus earlier generic market entry, several brand companies have in recent years sold or licensed authorized generics at the onset of this

180-day exclusivity period. The sale of authorized generics during the generic exclusivity period severely undercuts this incentive.

GPhA's Board of Directors supports Mylan's position that the brand company practices of selling or licensing authorized generics to undercut 180-day generic exclusivity are contrary to Hatch-Waxman and its basic goal of increased public access to affordable, generic drugs. Generic drugs account for over half of all prescriptions filled in the United States, but represent less than 10% of all drug expenditures. Public access to generic drugs is therefore critical to reducing health care costs in the United States. But the practice of selling "authorized generics" during the 180-day exclusivity period reduces the market share for the product enjoying the 180-day exclusivity; reduces the value of that exclusivity to the product's manufacturer; and, consequently, reduces the incentive for generic drug companies to challenge questionable patents and thereby expose expensive brand-name products to affordable generic competition. Accordingly, allowing the sale of authorized generics to continue would be fatal to one of the fundamental goals of Hatch-Waxman, which is designed to facilitate timely consumer access to affordable pharmaceuticals that compete with brand company products sold under questionable patents.

FDA has the authority "to promulgate regulations for the efficient enforcement" of the FDCA, including the Hatch-Waxman amendments. 21 U.S.C. § 371(a); United States v. Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 791-792 (1969) (noting that FDA, as the expert agency charged with enforcement of the FDCA, has the authority to issue regulations to protect the public health). The Agency also enjoys broad scope in the exercise of its regulatory authority. See Cosmetic, Toiletry & Fragrance Ass'n v. Schmidt, 409 F. Supp. 57, 64 (D.D.C. 1976) (noting FDA's "broad" regulatory authority); see also Young v. Community Nutrition Institute, 476 U.S. 974, 981 (1986) (noting that "the FDA has been delegated broad discretion by Congress in any number of areas" and deferring to Agency expertise).

FDA should exercise its broad regulatory authority to address practices that are directly contrary to the language and remedial goals of Hatch-Waxman.[1] The sale or licensing of authorized generics during the 180-day generic exclusivity period are such practices.

Authorized Generics Marketed During the First Generic Applicant's 180-Day Exclusivity Period Violate the Underlying Goals of Hatch Waxman.

One of Congress's primary goals in enacting Hatch-Waxman was to increase competition in the pharmaceutical arena by expediting the approval of lower-cost generic drugs. In re Barr Lab., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991) (noting that a key goal of

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[1] The Supreme Court has recognized that the FDCA in general is to be construed broadly given these remedial goals. Bacto-Unidisk, 394 U.S. at 798 (noting the "well-accepted principle that remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health").

Hatch-Waxman was to "get generic drugs into the hands of patients at reasonable prices – fast." (emphasis added). See also H.R. Rep. No. 98-857, pt. II (1984), reprinted in 1984 U.S.C.C.A.N. 2716-17 (declaring that one of the principal policy objectives of Hatch-Waxman was to "[g]et safe and effective generic substitutes on the market as quickly as possible after the expiration of a patent").

The 180-day exclusivity provision provides the first generic company to challenge a patent listed for the brand company product with statutory protection from generic competition. By providing this exclusivity, Congress gave generic drug manufacturers the incentive that they needed to expend the significant resources necessary to challenge or design/invent around suspect patents that otherwise might go unchallenged and to pave the way for eventual full generic competition. These patent challenges significantly accelerate consumer access to affordable pharmaceuticals and have saved American consumers and insurance providers billions of dollars. For example, the challenge to a patent claiming the brand drug Prozac expedited the marketing of a generic version of Prozac by two and a half years and saved consumers and healthcare providers approximately $2.5 billion. See generally Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration" (July 2002), at 16 ("FTC Report") (noting that generic patent challenges have succeeded in 73 percent of cases, resulting in consumer savings due to lower drug prices).

"The FDCA grants a period of exclusivity to the generic drug manufacturer who risked the possible infringement suit by the patent owner." Apotex Inc. v. Shalala, 53 F. Supp. 2d 454, 461 (D.D.C.), aff'd, 1999 WL 95686 (D.C. Cir. Oct. 8, 1999). As the Court in Apotex noted, "the purpose of the exclusivity incentive and the entire ANDA regime is to make available more low cost generic drugs." Id. The 180-day generic exclusivity is therefore a fundamental feature of the Hatch-Waxman regime, and one whose maintenance is critical to the success of that regime. The importance of the exclusivity incentive has only increased in recent years, during which brand companies have resorted with greater frequency to the use of suspect patents in an effort to stem generic competition. See FTC Report (noting increased efforts by generic companies to seek market entry prior to brand company patent expiration and success rate of generic patent challenges).

Allowing "authorized generics" to be marketed and distributed during the 180-day exclusivity period is directly contrary to the statutory provision since it undercuts the incentive for generic companies to take on questionable patents. Congress provided brand name companies with certain protections under the Hatch-Waxman Amendments. Allowing brand name companies to usurp the benefits explicitly provided to generic drug manufacturers is manifestly unfair and in direct contravention of the express will of Congress. As the court noted in Purepac Pharm. Co. v. TorPharm, Inc., 354 F.3d 877 (D.C. Cir. 2004), Hatch-Waxman contemplated that if a generic company challenged a patent, it was entitled to sell its generic drug product "without [generic] competition for 180 days." 354 F.3d at 879. Allowing authorized generics on the market during a first generic applicant's 180-day exclusivity period creates generic competition where the

statute intended none to exist, creating a huge unintended loophole that violates the spirit and letter of Hatch-Waxman.

Brand companies have argued that agreements to license authorized generics are actually *pro-competitive*, because they create generic competition more quickly. In enacting Hatch Waxman, however, Congress made the judgment providing the first filer with the exclusive right to market a generic drug for 180 days was the appropriate way to foster true competition in the long run by providing the generics an incentive to challenge questionable patents. In fact, authorized generic licensing agreements are simply yet another of the methods brand companies have increasingly resorted to in an effort to forestall generic competition. The end result of interfering with the 180-day exclusivity period is the devaluation of any incentive for challenging brand company patents in the first place. And the more brand company patents that go unchallenged (because the value of the diluted exclusivity makes patent challenges cost-ineffective), the longer brand company monopolies remain untouched by generic competition, and the longer consumers will be denied lower-cost generic drugs.[2]

FDA Should Issue Regulations Prohibiting the Marketing and Distribution of Authorized Generics During a First Generic Applicant's 180-day Exclusivity Period.

FDA should use its authority to issue regulations that foster the statutory scheme Congress created. GPhA urges FDA to modify its current regulations to eliminate, until the expiration of the 180-day exclusivity, a brand company's ability to make the labeling changes which are required for marketing an authorized generic. To further implement the policy of prohibiting the marketing of authorized generic products until expiration of the 180-day exclusivity, FDA should also require a certification by the brand company within a pre-approved supplemental application that the brand will not market the product as a generic drug until expiration of the exclusivity period. Under these requirements, FDA would withhold final authority to market authorized generics until expiration of a 180-day exclusivity period. Alternatively, as suggested in the Mylan petition, FDA could create a premarket registration requirement for authorized generics and prohibit their sale during the exclusivity period.

Under the FDCA, if a generic drug applicant wishes to market a product, it must file an ANDA under 21 U.S.C. § 355(j) and obtain approval from FDA. Because no ANDA may be approved during the pendency of an 180-day exclusivity period, the generic drug approval process ensures fidelity to the legislative purpose and the continued vitality of the generic incentive. Under FDA's current regulations, however, a brand company can make certain labeling changes that "do not involve a change in the

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[2] Authorized generic licensing agreements generally provide that the "generic" product not be marketed until after a true AB rated generic product has been approved, since to do so earlier would only diminish the profits received by the brand company by allowing a lower-priced generic to compete with the brand name product. Instead, these authorized generic agreements only go into effect once another generic product is marketed, resulting in the undercutting and devaluing of the 180-day exclusivity.

dosage strength or dosage form" without having to file a supplemental NDA to obtain prior approval from FDA. 21 C.F.R. 314.70(d)(2). Such changes, instead of having to be included in an NDA supplement, can be included in a brand company's annual report. Id. The brand companies have interpreted section 314.70(d)(2) as covering those labeling changes that are necessary to sell an authorized generic. These changes include packaging the product with a generic company's label and National Drug Code ("NDC") number. Under this scheme, brand companies have effected the sale of their NDA products as generic drugs for purposes of copayments and federal reimbursement, without having complied with the generic ANDA approval process. This practice, therefore, has been used by brand companies to end-run the ANDA system that preserves the strength of the generic exclusivity incentive and effectively vitiates that incentive.

FDA intended section 314.70(d)(2) to give brand manufacturers the flexibility to make routine changes to the labels on their products. It certainly did not intend to provide an avenue to sell a generic drug which directly competes with the generic product that was awarded 180-day generic exclusivity. Therefore, to remedy the unfair treatment of generic drug applicants who *have* complied with FDA requirements prior to marketing, FDA should amend its regulations to prohibit the introduction of a generic drug product until the expiration of the 180-day exclusivity period.

The Agency should prohibit efforts to undermine generic exclusivity through the sale of any drug product that is based on an NDA, other than the original brand product approved under that NDA, during the 180-day generic exclusivity period unless such a drug product is to be launched pursuant to an agreement with the holder of that exclusivity. First, FDA should amend section 314.70 so that any labeling changes required for the marketing of an authorized generic can only be made through a pre-approved supplemental application that cannot be made prior to expiration of the 180-day generic exclusivity period, which would include a certification that the authorized generic will not be sold until the expiration of the 180-day exclusivity period. This provision would, by definition, not apply to settlements between the generic and the brand where the generic selling the product during the 180-day period is itself entitled to the exclusivity. Alternatively, as suggested by Mylan, FDA could adopt a formal registration process that so that it could prohibit the marketing of any authorized generics until expiration of the exclusivity period.

Finally, FDA could issue a regulation prohibiting the marketing and distribution of authorized generics, as defined above, during the 180-day exclusivity period.

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Preservation of the 180-day exclusivity incentive remains one of GPhA's top priorities and we will continue to oppose efforts that decrease generic competition and raise the cost of prescription drugs to American consumers. Authorized generics are inconsistent with the purpose of the Hatch-Waxman Amendments to the FDCA and

undermine the incentives Congress created to balance innovation and competition. We urge the Agency to respond favorably to Mylan's petition and create a procedure for all in the industry to follow that would allow the first applicant to maintain its 180-day market exclusivity.

Respectfully submitted,

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GPhA